



Components of a Biosecurity Program

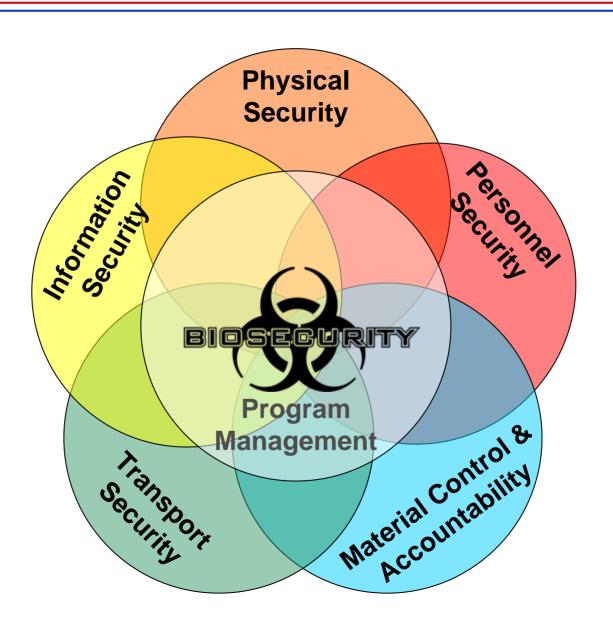
SNL Biosecurity Team
Chemical & Biological Weapons Nonproliferation
International Security Center
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Components of Biosecurity





Physical Security: System Elements

- Graded protection
- Access control
- Intrusion detection
- Alarm assessment and response







Physical Security: Concentric Layers of Security

Property Protection Areas

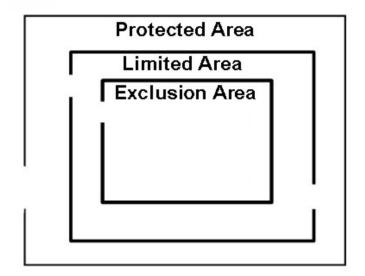
- Low risk assets
 - Grounds
 - Public access offices
 - Warehouses

Limited Areas

- Moderate risk assets
 - Laboratories
 - Sensitive or administration offices
 - Hallways surrounding Exclusion Areas

Exclusion Areas

- High risk assets
 - High containment laboratories
 - Computer network hubs





Physical Security: Property Protection Control

Fences

- Mark the boundaries of your property
- Announce your intention to protect the property
- Elicit strong statement of intent from intruder
- Terrain features can also serve this purpose





Physical Security:

Limited and Exclusion Area Access Control

- Access control ensures that only authorized individuals are allowed into certain areas
 - Increasingly strict controls as you move toward highest risk assets
- Limited Areas
 - Requires unique credential for access
 - Electronic key card, or
 - Controlled key
- Exclusion Areas
 - Requires unique credential <u>and</u> unique knowledge for access
 - Electronic key card <u>and</u> keypad or biometric device, or
 - Controlled key and second individual to verify identity





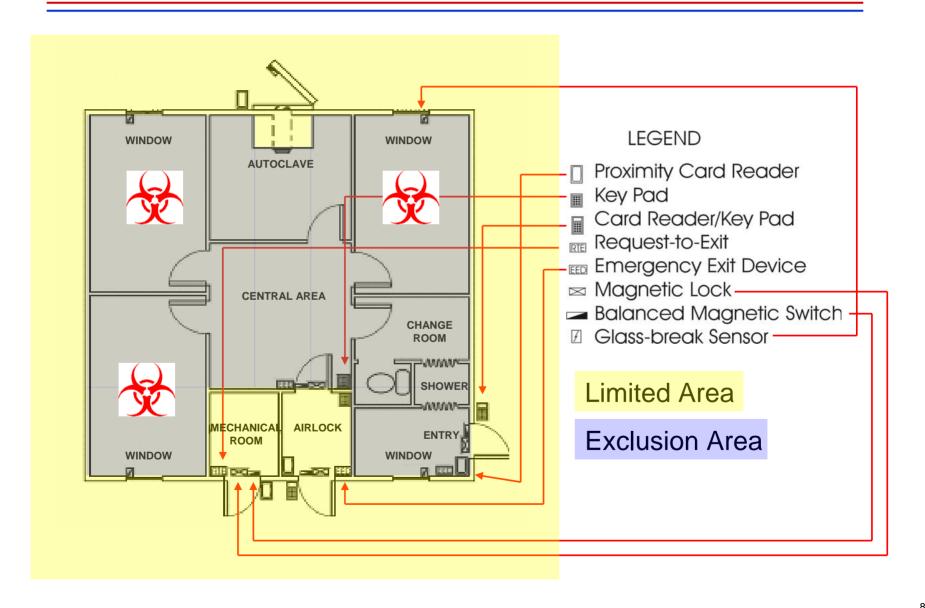


Physical Security: Intrusion Detection and Response

- Security violation detection
 - Guards
 - Electronic sensors
- Alarm assessment
 - Validation of violation before response
 - Can be direct (guards) or remote (video)
- On-site guard force response
 - Supports electronic systems
 - Patrols or guards perimeter and buildings
 - Summons and directs local law enforcement
- Local law enforcement (police) support
 - Reinforces or substitutes for on-site guard force
 - Memorandum of understanding



Physical Security: Example Laboratory Building





Physical Security: Procedures

- Examples of procedures that can be implemented to achieve graded protection
 - Impose consequences for security violations
 - Log personnel (including visitor) access to restricted areas including entry and exit times
 - Establish controls on animal and supply handling
 - Enforce escort policies
 - Visitors
 - Maintenance and cleaning personnel
 - Delivery personnel
 - Train personnel on what to do about:
 - Unrecognized persons
 - Unusual or suspicious activity



Physical Security:

Performance Testing and Maintenance

- Create security performance test plan and procedures
- Schedule periodic testing of hardware and policy implementation
- Schedule periodic testing of response force procedures
- Document test results
- Take corrective action
 - Schedule maintenance and repair of hardware
 - Corrective training and policy adjustments as appropriate for policy implementation failures
 - Corrective training and exercises for guard force



Personnel Security

- Personnel Screening
- Badges
- Visitor Control
- Training





Personnel Security: Screening

- Conduct screening for authorized individuals
 - Degree of scrutiny commensurate with level of risk associated with the position
 - Need for unescorted access to restricted areas
 - Types of assets held in the restricted areas
 - Level of authority in association with high risk materials
- Mechanisms
 - Verify credentials
 - Check references
 - Criminal history
 - In-depth background investigation





Personnel Security: Visitor Controls

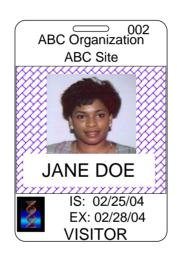
- Types
 - Personal Visitors
 - Family members
 - Casual Visitors
 - Tours, seminars
 - Equipment repair technicians
 - Working Visitors
 - Visiting researchers
 - Facility maintenance personnel
- Controls
 - All visitors should have a host at the facility
 - Visitors should be escorted in restricted areas



Personnel Security: Badges

 Badges should be issued to those individuals authorized to be in restricted areas







- Badge return
 - Upon employee termination
 - Daily or at the conclusion of a limited term for visitors
- Report lost or stolen badges



Personnel Security: In-Processing and Out-Processing

In-Processing

 Complete all required forms, safety training, security training and immunizations as applicable for work environment



- Access changes or termination
- Retrieve property
- Deactivate computer and electronic access accounts





Personnel Security: Employee Assistance Program

- Provide resources to address problems associated with a variety of personal issues
 - Marital issues
 - Family issues
 - Eldercare/childcare issues
 - Job conflict
 - Grief
 - Financial issues
 - Legal issues
 - Stress



Personnel Security: Security Violations

 Security violations should be ranked according to the effects upon the organization

Organization ABC keeps large quantities of HMUR agents in Building 1, Room 123, Freezer A.



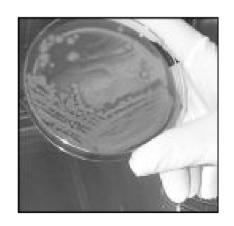
Material Control & Accountability: Objective

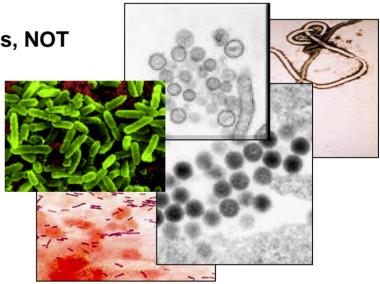
- Ensure the complete and timely knowledge of:
 - What materials exist
 - Where the materials are
 - Who is accountable for them
- NOT: to detect whether something is missing



Material Control and Accountability

- Defining "material" is complicated
- Agent
 - Name and description
- Quantity
 - Based on containers or other units, NOT number of microbes

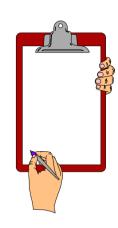


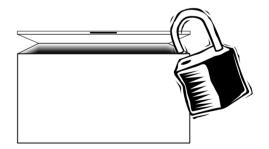




Material Control and Accountability

- Control is either...
 - Engineered / Physical
 - Administrative
- Containment is part of material control
 - Containment Lab / Freezer / Ampoule
- Procedures are essential for material control
 - For both normal and abnormal conditions







Material Control and Accountability

• All material should have an associated "accountable person"



Procedures should ensure accountability



Material Control & Accountability: Challenges and Benefits

- We want to avoid...
 - Implementing poor MC&A measures
 - Making "real work" more burdensome
 - Imposing unacceptable costs: time / money / effort
 - Spreading knowledge of inventory information

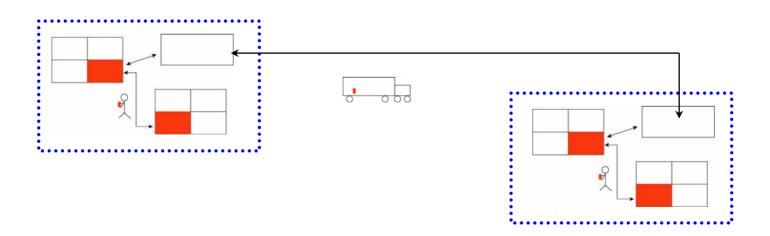
Benefits

- Prevents, or makes more difficult, some easy material diversion scenarios
- Documents lab status before any problems occur
 - Better than forensic work afterwards
- Is consistent with and reinforces good laboratory practice



Material Transport Security

- Why?
 - Dangerous pathogens and toxins are vulnerable to theft during movement outside of protected areas
- Who?
 - Facilities, carriers, and states all responsible
- The goal of transport security is
 - To mitigate the risk of theft during transport





Transport Security: Chain of Custody

- Aims to protect sample by documenting
 - All individuals who have control of sample
 - Secure receipt of material at appropriate location
- Chain of custody documentation includes
 - Description of material being moved
 - Contact information for a responsible person
 - Time/date signatures of every person who assumes control





Transport Security: Facility Responsibilities

- Personnel management
 - For people who have access to dangerous pathogens and toxins or information during transfers
- Establish chain of custody (CoC)
 - Record all individuals who have contact with the dangerous pathogens and toxins
- Provide physical security
 - For packages that need temporary storage
- Protect transport documentation
- Determine who is able to authorize, transport, and receive dangerous pathogens and toxins



Transport Security: Process

- Responsible authority pre-approves all transport
- Transport should be documented in lab records
- Transport is controlled and documented in delivery records
- Timely shipping methods are used
- Chain of Custody is maintained
- Notification of successful receipt



Information Security

- Protect information that is too sensitive for public distribution
 - Label information as restricted
 - Limit distribution
 - Restrict methods of communication
 - Implement network and desktop security
- Biosecurity-related sensitive information
 - Security of dangerous pathogens and toxins
 - Risk assessments
 - Security system design
 - Access authorizations





Information Security: Identification, Control, and Marking

Identification

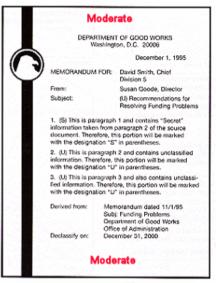
- Users of information should know the information's designated sensitivity level
- Levels of sensitivities should be based on standards
 - Low, Moderate, High
- A review and approval process aids in the identification of sensitivities
 - Critical for public release of information

Control

- The control of moderately and highly sensitive information should be the direct responsibility of the individual with the information
- This includes the physical security of the information and places where the information is stored
- In order to refuse public access upon request, information must be exempt from FOIA

Marking

- Moderately and highly sensitive information should be labeled in a consistent manner
 - Sensitivity level designation
 - Top and bottom of each page / cover sheet
- Marking and control methods should be well understood by those working with information







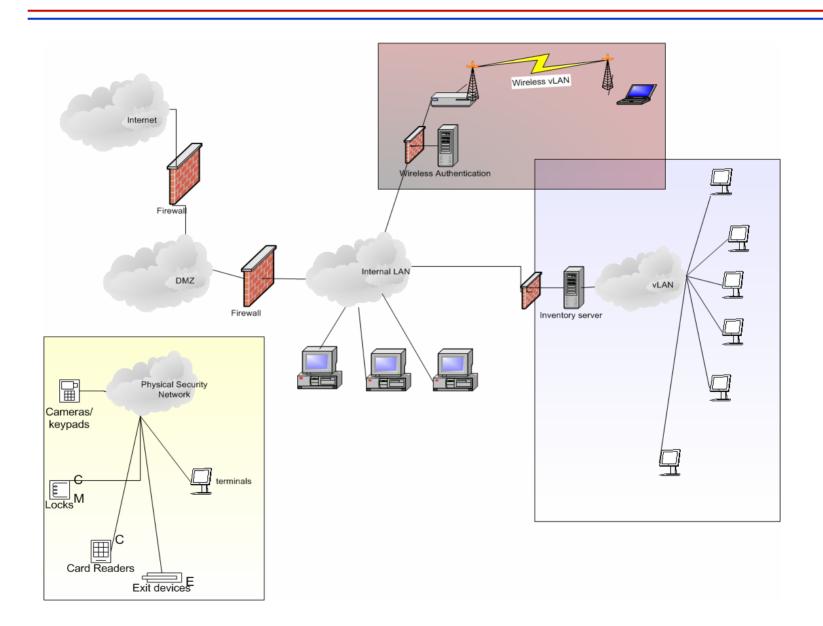
Information Security:

Communication and Network Security

- Insecure transmission of information can lead to accidental release
 - Mail, email, or fax security is required
 - Limited discussions in open areas
 - Information should only be reproduced when needed and each copy must be controlled as the original
- Network Management
 - The network on which all information is transmitted and systems on the network should be protected
 - Infrastructure
 - Servers
 - Network layered access
 - Desktop security
 - Remote access
 - Wireless



Example Network Design





Program Management: Responsibilities

- Identify the protection objectives of the biosecurity system
 - Distinguish between "unacceptable" and "acceptable" risks
 - Ensure that the cost to protect an agent is proportional to the risk of malicious use
- Design the system
 - Physical security
 - Security policies and procedures
- Write security and emergency response plans
- Conduct regular training and internal reviews
- Allocate resources







Program Management: Biosecurity Training

- Annual training tailored to different audiences
 - New and current employees
 - Managers
 - Emergency responders

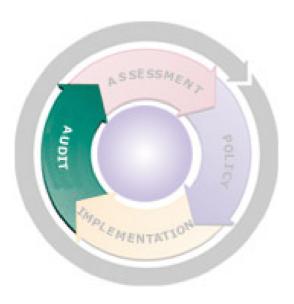




Program Management:

Self Assessments and Management Reviews

- Self assessments ensure compliance with standards and evaluate effectiveness of the biosecurity program
- Management reviews institute corrective and preventive actions, and allocate required resources





Program Management: Laboratory Biosecurity Plan

Develop laboratory biosecurity plan

- Facility mission and description
- Risk definition(s)
- Physical security
- Personnel management
- Material control and accountability
- Material transfer security
- Information security
- Biosecurity program management
- Incident response plans and reporting





Program Management: Policies



- Realistic policies
 - Policies should be comprehensive
 - Policies should allow for users to work as needed
- Understanding of policies by all users
 - Having clear policies is critical to users following them
 - The policies should be easy to locate, understand, and follow



Result of Biosecurity Risk Management

- Most pathogens and toxins would likely be LMUR
- Most current Select Agents would likely be MMUR
- Security associated with LMUR and MMUR would be achievable at reasonable cost for the broad biological research community
 - Rely largely on existing biosafety measures
- Very few Select Agents would be HMUR or EMUR
- Security for facilities that work with HMUR or EMUR would be relatively significant, but should still
 - Rely largely on policies and procedures
 - Be transparent to the users
 - Use resources efficiently
 - Not unnecessarily hinder normal operations (e.g. research, diagnostics, biosafety)



Conclusions

- Necessary to take steps to reduce the likelihood that the high risk agents, or any agents stipulated by government regulation, could be stolen from bioscience facilities
- Critical that these steps are designed specifically for biological materials and research so that the resulting system will balance science and security concerns
- Biological facility risk mitigation may be accomplished through an integrated biosecurity system that incorporates policies, procedures and equipment